STATE OF MICHIGAN

DEPARTMENT OF LABOR & ECONOMIC GROWTH

OFFICE OF FINANCIAL AND INSURANCE SERVICES

Before the Commissioner of Financial and Insurance Services

In the matter of

XXXXX
Petitioner **File No. 87334-001**
v

Blue Care Network of Michigan
Respondent
_____/

Issued and entered
This 5th day of March 2008
by Ken Ross
Commissioner

ORDER

I
PROCEDURAL BACKGROUND

On January 23, 2008, XXXXX (Petitioner) filed a request for external review with the Commissioner of Financial and Insurance Services (Commissioner) under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq*. On January 25, 2008, after a review of the material submitted, the Commissioner accepted the request for external review.

Because the case required analysis by a medical professional, the Commissioner assigned it to an independent review organization which submitted its recommendation to the Commissioner on February 6, 2007.

II
FACTUAL BACKGROUND

The Petitioner is a member of BCN, a health maintenance organization. The BCN 5 Certificate of Coverage (the certificate) and its prescription drug rider PD550C (the rider) define the Petitioner's benefits.

The Petitioner had back surgery in 2007. As a result, she is left with pain that is poorly controlled in the thoracic spine area. Petitioner requested coverage for Lidoderm patches, a nonformulary medication. BCN denied the request.

The Petitioner appealed and BCN maintained its denial. The Petitioner exhausted BCN's internal grievance process and appeals its final adverse determination dated January 10, 2008.

III
ISSUE

Did BCN properly deny the Petitioner authorization and coverage for the prescription drug Lidoderm?

IV
ANALYSIS

Petitioner's Argument

The Petitioner, on the advice of her surgeon, requested coverage for Lidoderm, a drug in the form of a patch form used to relieve pain. The Petitioner says that numerous other medications (Actonel and Miacalcin) and treatment failed to control her pain. She contends that without use of the patches she is not able to function or concentrate on her job due to the stabbing pain. When the pain begins, she is homebound and unable to work or perform activities of daily living.

In a letter dated September 24, 2007 her physician XXXXX, MD explained why the patches are medically necessary. Dr. XXXXX stated in part:

> I have been seeing Petitioner as a patient since 12/20/06 and she had continuous complaints of significant mid thoracic pain. Her imaging studies revealed she had a compression fracture on the T8 vertebral body in which I performed a kyphoplasty on in June of 2007. The patient has osteoporosis and at the time of the kyphoplasty due to multiple insufficiencies in the bone and as the cement fill was not complete; she did get some relief but not complete relief. She still suffers from significant chronic mid thoracic pain that at times can be disabling.
>
> Due to her significant discomfort and at this point an exhaustion of other

> possible treatment options, the only thinking that is currently providing some form of relief is the Lidoderm patches that we have been providing for no charge because Blue Care Network will not cover this expense for the patient.
>
> It is my medical opinion that this is a medical necessity as all other surgical and non-surgical options have been exhausted to provide her with any form of satisfactory relief and to maintain the patient at a functional lifestyle.

The Petitioner and her physician believe BCN should provide coverage for Lidoderm because it is medically necessary for the relief of her pain.

BCN's Argument

In its January 10, 2008 final adverse determination, BCN denied coverage for Lidoderm. The final adverse determination states:

> Based on the information received, the Panel determined that Lidoderm 5% patch has not been approved by the Food and Drug Administration (FDA) for the treatment of your medical condition.

BCN says that the drug is not a covered benefit and its denial was appropriate.

Commissioner's Review

Generally, the Petitioner only has coverage for prescription drugs that are on the BCN formulary and Lidoderm is not on the formulary. However, the rider recognizes that there are exceptions to the formulary limitation under certain conditions, e.g., a non-formulary prescription drug may be covered if it is medically necessary. The rider defines "covered drug" as:

> COVERED DRUG means a Generic drug, brand Name Prescription Drug, a compounded Medication, or a health habit Prescription Drug which is: a) included in and dispensed in accordance with the BCN Formulary; b) prescribed by a BCN Affiliated Provider; and c) obtained through a Participating Pharmacy. . . . A non-formulary drug is also a Covered Drug when the BCN Affiliated Provider and BCN agree that it is medically necessary and the prescription for the drug is preauthorized. [Emphasis added]

Moreover, there are two provisions in the Michigan Insurance Code that require exceptions to formulary limitations when non-formulary prescription drugs are medically

necessary. The first, of general application, is Section 3406o (MCL 500.3406o):

> An insurer [or HMO] that delivers, issues for delivery, or renews in this state an expense-incurred hospital, medical, or surgical policy or certificate that provides coverage for prescription drugs and limits those benefits to drugs included in a formulary shall do all of the following:
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> * * *
>
> (c) Provide for exceptions from the formulary limitation when a non-formulary alternative is a medically necessary and appropriate alternative. This subdivision does not prevent an insurer from establishing prior authorization requirements or another process for consideration of coverage or higher cost-sharing for non-formulary alternatives. Notice as to whether or not an exception under this subdivision has been granted shall be given by the insurer within 24 hours after receiving all information necessary to determine whether the exception should be granted. [Emphasis added]

The second provision is in Section 3406q (MCL 500.3406q) which applies specifically to off-label use of medications. It says in part:

> Off-label use of approved drug; coverage; conditions; compliance; use of copayment, deductible, sanction, or utilization control; limitation; definitions.
>
> 1. An expense-incurred hospital, medical, or surgical policy or certificate delivered, issued for delivery, or renewed in this state that provides pharmaceutical coverage and a health maintenance organization contract that provides pharmaceutical coverage shall provide coverage for an off-label use of a federal food and drug administration approved drug and the reasonable cost of supplies medically necessary to administer the drug.
> 2. Coverage for a drug under subsection (1) applies if all of the following conditions are met:
>
> (a) The drug is approved by the federal food and drug administration.
>
> (b) The drug is prescribed by an allopathic or osteopathic physician for the treatment of either of the following:
>
> (i) A life-threatening condition so long as the drug is medically necessary to treat that condition and the drug is on the plan formulary or accessible through the health plan's formulary procedures.
>
> (ii) A chronic and seriously debilitating condition so long as the drug is medically necessary to treat that condition and the drug is on the plan formulary or accessible through the health plan's formulary procedures.
>
> (c) The drug has been recognized for treatment for the condition for which it is prescribed by 1 of the following:

(i) The American medical association drug evaluations.

(ii) The American hospital formulary service drug information.

(iii) The United States pharmacopoeia dispensing information, volume 1, “drug information for the health care professional”.

(iv) Two articles from major peer-reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal.

3. Upon request, the prescribing allopathic or osteopathic physician shall supply to the insurer or health maintenance organization documentation supporting compliance with subsection (2).

4. This section does not prohibit the use of a copayment, deductible, sanction, or a mechanism for appropriately controlling the utilization of a drug that is prescribed for a use different from the use for which the drug has been approved by the food and drug administration. This may include prior approval or a drug utilization review program. Any copayment, deductible, sanction, prior approval, drug utilization review program, or mechanism described in this subsection shall not be more restrictive than for prescription coverage generally.

5. As used in this section:

(a) “Chronic and seriously debilitating” means a disease or condition that requires ongoing treatment to maintain remission or prevent deterioration and that causes significant long-term morbidity.

(b) “Life-threatening” means a disease or condition where the likelihood of death is high unless the course of the disease is interrupted or that has a potentially fatal outcome where the end point of clinical intervention is survival.

(c) “Off-label” means the use of a drug for clinical indications other than those stated in the labeling approved by the federal food and drug administration.

Section 3406q requires an HMO like BCN that provides outpatient pharmaceutical coverage to cover the off-label use of medications when it is medically necessary, prescribed by a physician and meets certain criteria. In this case, the Lidoderm was a prescribed by a physician (Dr. XXXXX) who determined the drug is medically necessary. To help the Commissioner resolve the issue of whether Lidoderm is medically necessary and appropriate,

the matter was assigned to an independent review organization (IRO) for the recommendation of an expert.

The IRO physician reviewer is board certified in anesthesiology. The reviewer recommended reversing BCN's denial of coverage. The IRO report includes the following statements:

> The standard diagnostic and therapeutic interventions for patients with chronic back pain depend on the underlying etiology of the pain. Such interventions may include but are not limited to: MRI of spine, bone scan, fluoroscopy, epidural steroid injection, facet injections/ablation therapy, trigger point injections, spine surgery, intrathecal pain pump, oral medications . . . physical and occupational therapy.
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> * * *
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> In the professional opinion of the Reviewer and based on the current literature, transdermal patch of lidocaine 5% is not an experimental or investigational medication as defined by the health plan contract. Specifically, transdermal lidocaine has been demonstrated to be a safe method to deliver topical lidocaine.
>
> [Th]e use of the transdermal lidocaine 5% patch is acceptable when used in combination with other treatment modalities such as oral medications, especially in patients who demonstrate a positive response – decreased pain symptoms. Based on the reports of decreased pain symptoms, the transdermal lidocaine patch is medically necessary in [Petitioner's] case.

The IRO reviewer's recommendation, based on extensive expertise and professional judgment, is afforded deference by the Commissioner. The Commissioner can discern no reason why the IRO reviewer's judgment should be rejected in the present case. Therefore, the Commissioner accepts the IRO reviewer's conclusion that Lidoderm is not investigational and is medically necessary for the Petitioner. BCN is required to cover the drug as an exception to its formulary limitation.

V
ORDER

BCN's January 10, 2008, final adverse determination is reversed. BCN shall authorize coverage for the Lidoderm patches within 60 days of the date of this Order. BCN shall, within seven days of providing coverage, provide the Commissioner proof it has implemented the

Commissioner's Order. To enforce this Order, the Petitioner must report any complaint regarding the implementation of this Order to the Office of Financial and Insurance Services, Health Plans Division, toll free 877-999-6442.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than sixty days from the date of this Order in the Circuit Court for the county where the covered person resides or in the Circuit Court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of the Office of Financial and Insurance Services, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.